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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/517,597	03/02/2000	Wah Y. Wong	4800-0015.30	4305

7590 04/17/2002

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EXAMINER

PADMANABHAN, KARTIC

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 04/17/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/517,597

Applicant(s)

WONG ET AL.

Examiner

Kartic Padmanabhan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Terminal Disclaimer

1. The terminal disclaimer filed on January 11, 2002 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patent 6,300,141 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Information Disclosure Statement

2. The information disclosure statement filed July 2, 2001 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but those references not initialed have not been considered.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the way in which the reaction of the liquid sample and an analyte reacting reagent forms a solution of a fort coil-forming peptide, as well as the way in which determination of whether the coiled-coil heterodimer has formed is indicative of analyte

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presence. Since the reaction step of the sample and analyte reacting reagent seemingly does not include the coil forming peptide in any way, it is unclear how a solution of this peptide is formed from this reaction. Applicant must include some correlation between the steps. In addition, the body of the claim does not appear to be consistent with the preamble because applicant has not included any correlation steps in the body to indicate how analyte presence is determined. In addition, what happens in the absence of analyte? It appears that the coiled-coil heterodimer will still form. Therefore, how can this method, as recited, be used to determine analyte presence, if only formation of the heterodimer is being determined?

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

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evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lennox et al. (WO 97/41424).

Lennox et al. teach a biosensor device and method, wherein the apparatus includes a biosensor surface and surface-bound two-subunit heterodimer complexes composed of first and second oppositely charged peptides that together form an alpha-helical coiled-coil heterodimer. The first peptide is attached to the biosensor surface, and the second peptide carries the ligand, accessible for binding by a ligand-binding agent. Binding is detected by a suitable detector. The biosensor surface can be prepared by the addition, to a template containing the first charged peptide, of a selected ligand attached to the second charged peptide. In a preferred embodiment, the biosensor surface includes a monolayer of hydrocarbon chains anchored at their proximal ends to the biosensor surface, and having free distal ends defining an exposed monolayer surface. The heterodimer complexes are preferably embedded within the monolayer, which is closely packed and ordered to form an effective barrier to current across the monolayer mediated by a redox ion species in an aqueous solution in contact with the monolayer. Binding of a ligand-binding agent to the ligand on the monolayer surface will increase current across the monolayer. The analyte of interest, which may be an anti-ligand binding agent, or a ligand or ligand analog that will compete with surface bound ligand for binding to a ligand-binding agent, will be introduced into a chamber of the biosensor. The chamber is filled with a solution containing an

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analyte and ionic species capable of undergoing a redox reaction at a charged electrode.

Exemplary redox species are $\text{Fe}(\text{CN})_6^{3-}$ as a negatively charged species and $\text{Ru}(\text{NH}_3)_6^{3+}$ as a positively charged species. The analyte may be in free form or part of a complex. When the analyte is a ligand or ligand analog, there will be a ligand binding agent that may be immobilized on the chamber walls or present in unbound form within the chamber. A detector will determine the level of binding of ligand binding agent to the surface ligands. The pairing of the two oppositely charged peptides to form charge-neutral heterodimers in the monolayer results in a reduction in monolayer conductance. The reference does not specifically teach the effect of the redox ion species on current, nor does it teach the competitive nature of the assay.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the method of Lennox et al. to obtain the claimed invention. Although Lennox et al. does not teach the reaction of a sample with a reaction reagent to obtain a first coil-forming peptide, it would have been obvious to do so. Incorporation of the analyte ^{reaction reagent} into the first coil forming peptide before reaction with the second coil forming peptide would have had the advantage of requiring fewer steps to carry out the process of determination of analyte presence. In addition, whether the analyte is contacted with the first coil-forming peptide before contact with the second peptide, or whether the analyte was contacted after heterodimer formation, the end result would have been the same, and one of ordinary skill in the art would have recognized that either protocol could have been used with a reasonable expectation of success. Furthermore, the recitation of relating the amount of unbound conjugate to the amount of analyte present in the sample is rendered obvious by the method of Lennox et al., as this recitation simply amounts to a competitive solid phase assay, which is well known in the art. As more analyte contacts its

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corresponding receptor, the conjugate is displaced (becomes unbound). Therefore, increasing analyte amounts results in decreasing conjugate amounts. It would have further been obvious at the time of the invention that a redox ion species that has the same charge as the second coil forming peptide would enhance ion-mediated current flow across the monolayer because the repulsion of like charges would disrupt the monolayer and allow flow through the barrier. Conversely, if the redox ion species has a charge opposite of the second coil forming peptide, there will be no repulsion and the monolayer will be stabilized, resulting in reduced current flow through the monolayer. Since $\text{Fe}(\text{CN})_6^{3-}$ has been disclosed as a suitable negatively charged species and $\text{Ru}(\text{NH}_3)_6^{3+}$ as a suitable positively charged species, it would have been obvious to use these ion carriers in the modified method.

Response to Arguments

10. Applicant's arguments filed January 11, 2002 have been fully considered but they are not persuasive to overcome the 103 rejection over Lennox et al.

11. Applicant's arguments that the reaction of a liquid sample and analyte reaction reagent to form a solution of first coil-forming peptide is not inherent in the reference of Lennox et al., as proposed by the examiner, is accurate. However, the examiner maintains that this format would have been obvious in view of the Lennox reference, as one would have realized that any assay format would have worked in achieving the same end results.

12. Applicant's claim that the recited method provides several advantages over the prior art is moot, as limitations attesting to this fact have not been incorporated into the claims.

Conclusion

Claims 1-10 are rejected.


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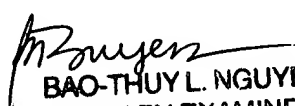
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 703-305-0509. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-5207 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Kartic Padmanabhan
Patent Examiner
Art Unit 1641


April 10, 2002


BAO-THUY L. NGUYEN
PRIMARY EXAMINER
4/16/02